Supreme Court, U.S.
FILED
AUG 6 1998
OFFICE OF THE CLERK

No. 98 245

In The

Supreme Court of the United States

October Term, 1997

HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc.,

Petitioner,

vs.

GEORGE E. ELBERT,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

GOODSILL ANDERSON QUINN & STIFEL
JACQUELINE L.S. EARLE*
MARGARET JENKINS LEONG
1099 Alakea Street, Suite 1800
Honolulu, Hawaii 96813
Ph: (808) 547-5600

Counsel for Petitioner

**Counsel of Record*

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

48 pp

QUESTION PRESENTED

Whether the Ninth Circuit erred by holding, in direct conflict with opinions of the Third Circuit, that a district court considering a post-verdict motion for judgment must give weight to expert testimony deemed unreliable on appeal.

PARTIES TO THE PROCEEDING

Petitioner Howmedica Inc. is a wholly-owned subsidiary of Pfizer Inc.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

PARTIES TO THE PROCEEDING ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES iv

PETITION FOR WRIT OF CERTIORARI 1

OPINIONS BELOW 2

STATEMENT OF JURISDICTION 2

STATEMENT OF THE CASE 2

A. The First Trial 2

B. The First Appeal 4

C. Proceedings on Remand 5

D. The Second Appeal 6

REASONS FOR GRANTING THE WRIT 7

I. THIS CASE PRESENTS AN ISSUE AS TO WHICH CIRCUIT COURTS ARE IN DIRECT CONFLICT 7

II. THIS ISSUE IS OF CONSIDERABLE IMPORTANCE IN THE POST-*DAUBERT* WORLD 12

CONCLUSION 15

APPENDIX ..... App. 1

TABLE OF AUTHORITIES

Page

FEDERAL CASES

Aloe Coal Co. v. Clark Equipment Co., 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987) 7, 8, 9

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) 1, 6, 11, 12, 13, 14

Elbert v. Howmedica, Inc., a Division of Pfizer Hospital Products Group, Inc., 143 F.3d 1208 (9th Cir. 1998) 2

Douglas v. Eaton Corp., 956 F.2d 1339 (6th Cir. 1992) 9

Jackson v. Pleasant Grove Health Care Ctr., 980 F.2d 692 (11th Cir. 1983) 9, 11

Lightening Lube, Inc. v. Witco Corp., 4 F.3d 1153 (3d Cir. 1993) 7, 9, 10, 11

Lippay v. Cristos, 996 F.2d 1490 (3rd Cir. 1993) 10

Midcontinent Broadcasting Co. v. North Central Airlines, Inc., 471 F.2d 357 (8th Cir. 1973) 8, 9, 10, 11, 12

Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 61 S. Ct. 189, 85 L. Ed. 147 (1940) 10

Price v. Seydel, 961 F.2d 1470 (9th Cir. 1992) 14

Raynor v. Merrell Pharmaceuticals, Inc., 104 F.3d 1371 (D.C. Cir. 1997) 12

Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C. Cir. 1988) 12

TABLE OF AUTHORITIES – Continued

Page

Schudel v. General Electric Co., 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S. Ct. 1560 (1998) 6, 7, 8, 10, 11, 12

Sumitomo Bank v. Product Promotions, Inc., 717 F.2d 215 (5th Cir. 1983) 8

Summers v. Missouri Pacific R.R. System, 132 F.3d 599 (10th Cir. 1997) 14

STATE CASES

Townsend v. United States Rubber Co., 74 N.M. 206, 392 P.2d 404 (N.M. 1964), *overruled on other grounds, Rhein v. ADT Automotive, Inc.*, 122 N.M. 646, 930 P.2d 783 (N.M. 1996) 8

FEDERAL STATUTES

28 U.S.C. § 1254(1) 2

Fed. R. Civ. P. 16 13

Fed. R. Civ. P. 50(b) 1, 6, 7

PETITION FOR WRIT OF CERTIORARI

Petitioner Howmedica Inc. prays that a writ of certiorari issue to review the judgment and opinion of the Ninth Circuit entered in this proceeding on May 8, 1998, in order to resolve a direct conflict with the Third Circuit on the question of whether evidence improperly admitted at trial should be considered upon a post-verdict motion for judgment under Rule 50(b) of the Federal Rules of Civil Procedure. This case presents an excellent opportunity for exercise of this Court's certiorari jurisdiction, because review would resolve a clear split between the circuits. The split will not resolve on its own, because the Third Circuit has repeatedly and emphatically rejected the reasoning espoused by the Ninth Circuit, and the Ninth Circuit has acknowledged but failed to address the Third Circuit's criticism. If allowed to stand, the Ninth Circuit's decision will greatly increase the caseload and administrative expenses of the federal courts, because it mandates a new trial in all cases where evidence is held inadmissible after verdict or on appeal. The Ninth Circuit's adoption of a blanket rule poses a particular threat to the vitality of this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), because it gives a party whose witness was struck under *Daubert* the right to name a new expert in an area already held lacking in scientific validity.

OPINIONS BELOW

The decision of the Ninth Circuit Court of Appeals in *Elbert v. Howmedica, Inc., a Division of Pfizer Hospital Products Group, Inc.*, CV-91-00616 BMK, is reported at 143 F.3d 1208 (9th Cir. 1998) (Appendix "App." 1). The judgment of the District Court for the District of Hawaii which was the subject of this appeal (App. 7) is not reported. The prior decision of the Ninth Circuit Court of Appeals in this case reversing the judgment in favor of plaintiff (App. 22) is not reported. 59 F.3d 174 (table) (9th Cir. 1995).

STATEMENT OF JURISDICTION

The judgment of the Ninth Circuit Court of Appeals was filed and entered May 8, 1998. The jurisdiction of this Court is timely invoked under 28 U.S.C. § 1254(1).

STATEMENT OF THE CASE

A. The First Trial

Respondent filed this product liability suit, involving a Porous Coated Anatomic Primary Knee prosthesis manufactured by Petitioner ("P.C.A. Knee"), in the state court in Hawaii in October 1991. Petitioner removed the suit to the United States District Court for the District of Hawaii on October 31, 1991.

During the pretrial phase of the case, several rulings were issued limiting Respondent's ability to present expert testimony. In mid-March, 1993, Petitioner took the

depositions of the two experts identified by Respondent. One, Kenneth Kayser, was an electrical engineer who had no prior experience with prosthetic knees or with the ultra-high molecular weight polyethylene that had allegedly failed in Respondent's P.C.A. Knee. On the basis of several articles, some of which had been furnished to him by Respondent's attorney, he stated opinions both as to Petitioner's standard of care and as to proximate causation. The other expert, Curtis Watts, an aeronautical engineer, also had no prior experience with prosthetic knees or with ultra-high molecular weight polyethylene. Mr. Watts, however, was not prepared to state any opinions as of the time of his deposition. On March 31, 1993, almost four months after his deadline for naming experts, Respondent belatedly identified eight new expert witnesses. Petitioner brought an expedited discovery motion to strike the new experts and to limit the testimony of Messrs. Kayser and Watts and for sanctions as to the unprepared Mr. Watts. Following a hearing, the Court entered an order on May 24, 1993 stating that: "The new witnesses may not be called by plaintiff as expert witnesses and may not testify on issues of liability and/or causation in this case." As to the unprepared expert, Respondent was ordered to fly Mr. Watts to Honolulu and to pay all costs for three hours of additional deposition time. These rulings were not challenged on appeal.

Trial in the case commenced August 3, 1993. Respondent proceeded on the theory that a proprietary heat-pressing method used by Petitioner in the manufacture of the ultra-high molecular weight polyethylene tibial insert of the P.C.A. Knee had caused Respondent's tibial insert

to delaminate. The only expert Respondent offered at trial on the issues of standard of care and causation was Kenneth Kayser, who, as stated, had no training on or familiarity with the manufacture or use of prosthetic knee joints or the polyethylene component at issue. The trial court denied Petitioner's motion to exclude Mr. Kayser's testimony. Mr. Kayser testified that Howmedica had failed to adhere to reasonable manufacturing practices and that its negligence had caused Respondent's injury.

Petitioner moved for judgment as a matter of law at the close of Respondent's case, arguing that Mr. Kayser's testimony was not reliable or entitled to weight and that, as a consequence, Respondent had failed to satisfy its evidentiary burden. The court, acknowledging that the question of Mr. Kayser's expert testimony was a "close one," denied the motion. The jury returned a verdict for Respondent on the counts of negligence and breach of warranty and for Petitioner on the strict product liability claim. After the verdict was entered, Petitioner renewed its motion for judgment as a matter of law. The court denied Petitioner's post trial motion, noting that the evidence was sufficient based upon Mr. Kayser's testimony. Petitioner appealed.

B. The First Appeal

In June 1995, the Ninth Circuit reversed the judgment in favor of Respondent on the grounds that Mr. Kayser should not have been deemed qualified to testify. App. 22. The Ninth Circuit found that Mr. Kayser had "presented no evidence on his experience or qualifications regarding the specific subject areas in which he offered

testimony." App. 24. The court noted that Mr. Kayser's testimony was essential to Respondent's case, since "Kayser was the only witness who offered testimony asserting that Howmedica could have known and should have known its P.C.A. Knee would delaminate and thereby produce Elbert's injury." App. 24. The court found, moreover, that "[t]he jury's award against Howmedica for negligence and breach of warranty, despite its finding of no strict liability, is strong evidence that the testimony was prejudicial." The Ninth Circuit did not order a new trial, but remanded for proceedings consistent with its opinion.

C. Proceedings on Remand

Following remand of the case, the parties filed cross-motions based on their differing views of "proceedings consistent with" the Ninth Circuit's decision. Petitioner moved for entry of judgment in its favor, arguing that Respondent's evidence was insufficient without Mr. Kayser to establish the elements of standard of care and causation. Respondent moved for a new trial, urging that he had enough evidence to sustain a verdict even without Mr. Kayser's testimony. Respondent urged that the testimony of his remaining experts would suffice, and that no expert testimony was necessary to establish his cause of action in any event. He did not argue that he should be permitted to call an additional expert witness to replace Mr. Kayser's testimony and did not indicate that he intended to retain a new expert if a new trial were granted.

After hearing, the trial court granted judgment for Petitioner. App. 7. The court considered the testimony of

each of Respondent's remaining witnesses and found that none rendered testimony on standard of care or causation. The trial court found that "absent Kayser's testimony, there was insufficient evidence of negligence or breach of implied warranty by Howmedica to support the jury verdict in favor of Respondent." App. 20.

D. The Second Appeal

By published opinion, a different panel of the Ninth Circuit (Reinhardt, Leavy and Thomas), reversed the trial court and remanded for further proceedings. App. 1. The basis for the court's decision was a theory that Respondent had not urged at trial or on appeal: that a trial court considering the sufficiency of the evidence on a post-appeal motion for judgment had to consider evidence which, like Mr. Kayser's testimony, had been improperly submitted to the jury. App. 3. The panel applied the recent decision in *Schudel v. General Electric Co.*, 120 F.3d 991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. 1560 (1998),[1] which held that, in considering the sufficiency of evidence on a Rule 50(b) motion, the trial court must give weight even to evidence that had been admitted in error under *Daubert*.

The panel determined that weight must be given to Kayser's improper testimony because the plaintiff had relied on the trial court's initial finding of admissibility in presenting his case.

> This rule promotes certainty: litigants need not supplement conditionally admitted evidence,

---

[1] Petitioner in *Schudel* did not seek certiorari on this issue.

> perhaps, unnecessarily; and district courts need not speculate as to what other evidence might have been offered if the evidence had been excluded at trial. The rule promotes fairness: punishing a litigant for the court's erroneous admission of evidence is unfair; and the remedy of a new trial is available to both sides on equal footing.

App. 3 (quoting *Schudel*). The panel did not consider whether Respondent would or could have furnished an expert to replace Mr. Kayser if his testimony had been excluded during trial, nor did its holding give the trial court any discretion to do so. The panel concluded that it was error to deny Respondent's new trial motion since Petitioner's Rule 50(b) motion following remand should have been denied.

REASONS FOR GRANTING THE WRIT

I. THIS CASE PRESENTS AN ISSUE AS TO WHICH CIRCUIT COURTS ARE IN DIRECT CONFLICT.

There is a conflict among the Circuit Courts of Appeal on the question presented in this case. In *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987), and *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993), the United States Court of Appeals for the Third Circuit emphatically rejected the reasoning adopted by the Ninth Circuit in *Schudel* and the case below. If the Third Circuit's analysis had been controlling in this case, the trial court's entry of judgment would have been sustained on appeal.

The decisions below and in *Schudel* expand upon a 1973 decision from the Eighth Circuit Court of Appeals, *Midcontinent Broadcasting Co. v. North Central Airlines, Inc.*, 471 F.2d 357 (8th Cir. 1973), which in turn is based on a 1964 New Mexico Supreme Court decision, *Townsend v. United States Rubber Co.*, 74 N.M. 206, 392 P.2d 404 (N.M. 1964), *overruled on other grounds, Rhein v. ADT Automotive, Inc.*, 122 N.M. 646, 930 P.2d 783 (N.M. 1996). *Midcontinent* and *Townsend* held that a trial court may not disregard improperly admitted evidence on a motion for judgment notwithstanding the verdict ("JNOV") because the proponent of the evidence relied on the court's initial finding of admissibility and would presumptively have offered better or different evidence at trial if the objection had been timely sustained. In 1983, the Fifth Circuit Court of Appeals also endorsed this view. *Sumitomo Bank v. Product Promotions, Inc.*, 717 F.2d 215, 218 (5th Cir. 1983).

In *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987), the Third Circuit Court of Appeals sharply criticized the decisions above:

> We have carefully examined the opinions from the Fifth and Eighth Circuits and New Mexico, but regrettably we find no reasoned elaboration to support their thesis. . . . The longest discussion appears in New Mexico's *Townsend* case which, upon analysis, is one conclusory statement piled on another. *Townsend*, 392 P.2d at 406. What follows is a classic case of precedential inbreeding, where decisions multiply and parrot a holding, with no court pausing, first, to identify the competing social, public, or private interests involved, then, to resolve the possible

> conflicts, and finally, to give the public reasons for the resolution.

Aloe Coal, 816 F.2d at 115 (some internal citations omitted). The Third Circuit disagreed that detrimental reliance by the party offering testimony is a sufficient reason for giving weight to inadmissible evidence after trial. "This explanation, of course, does not address either the competing reliance concerns of the defendant, or the homespun axioms that a litigant is entitled to only one bite of the apple or only three strikes at bat." *Id.* at 116.

The strong language of *Aloe Coal* was not essential to its holding, because the Third Circuit found that plaintiff had failed to allege a cognizable injury under state products liability law. In 1993, when the Third Circuit was squarely presented with the issue, it held that improperly-admitted testimony need not be considered when resolving a renewed motion for judgment. *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1199-1200 (3d Cir. 1993).

In *Lightening Lube*, the Third Circuit reaffirmed the reasoning of *Aloe Coal*, and renewed its earlier pointed criticism of the *Midcontinent* approach. The court acknowledged that two other Circuits had joined the *Midcontinent* line since *Aloe Coal* was decided. 4 F.3d at 1199 (citing *Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d 692 (11th Cir. 1983); and *Douglas v. Eaton Corp.*, 956 F.2d 1339 (6th Cir. 1992)). Again dismissing the *Midcontinent* approach as "precedential inbreeding," the Third Circuit repeated *Aloe Coal*'s complaint that the majority lacked a sound rationale and failed to consider the consequences of their decisions, and expressly noted that the

Supreme Court had yet to resolve the issue. 4 F.3d at 1199 & n. 26.[2]

Lightening Lube explored and rejected *Midcontinent*'s major premise that the party offering the improper testimony changes its position in reliance upon the trial court's preliminary admission: "[W]e find no reason to suppose that a litigant would hold back significant evidence at trial." 4 F.3d at 1199-1200. The court looked at the facts of the case before it and determined that no reliance had been shown:

> Indeed, Lightening Lube has not pointed to any additional evidence of the culpability of Witco's management that it withheld at trial, but would have introduced had it known that the court ultimately would rule evidence of the state of mind concerning the counterclaim to be inadmissible.

Id. Lightening Lube also cited with approval another 1993 decision in which another Third Circuit panel (Becker, Greenberg, and Weiss) held that the trial court should have discretion to choose between new trial and JNOV when evidence was struck on appeal. *Id.* at 1199 (citing *Lippay v. Cristos*, 996 F.2d 1490, 1501 (3rd Cir. 1993)).

Schudel v. General Electric Co., 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S. Ct. 1560 (1998), was the first case to decide the question presented after the split in the

---

[2] The *Midcontinent* panel had found support for its position in a 1940 case, *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 85 L. Ed 147 (1940), *see Midcontinent*, 471 F.2d at 357, but the Third Circuit disputed that *Montgomery Ward* had any application. 4 F.3d at 1199.

circuits arose. The Ninth Circuit noted that the Third Circuit had rejected *Midcontinent*'s central tenet of reliance. *Schudel*, 120 F.3d at 995 n. 10 (citing *Lightening Lube)*. However, *Schudel* went on to adopt *Midcontinent* on reliance grounds without even attempting to address the question *Lightening Lube* raised. *See* 120 F.3d at 995 ("If evidence is ruled inadmissible during the course of trial, the plaintiff has the opportunity to introduce new evidence. However, when that evidence is ruled inadmissible in the context of deciding a motion for JNOV, the plaintiff, having relied on the evidence already introduced, is unable to remedy the situation.") (quoting *Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d at 696).

Schudel was the first case to apply *Midcontinent* to the testimony of an expert witness whose scientific knowledge was judged unreliable under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). After a jury verdict for plaintiffs, the trial court reconsidered its decision to admit expert testimony linking plaintiffs' neurological complaints to exposure to cleaning solvents. The Ninth Circuit affirmed that this expert testimony should have been excluded. 120 F.3d at 997. However, the panel went on to hold that the trial court must give weight to the unreliable expert opinion in ruling on defendants' Rule 50(b) motion, based on *Midcontinent*'s presumption that plaintiff could have produced better evidence if the original expert had been excluded during trial. The *Schudel* court did not consider whether the trial court's finding of unreliability under *Daubert* made it unreasonable to presume that plaintiffs would find another witness to support their case.

The decision below reaffirms this unexamined presumption of reliance in *Schudel*. The Ninth Circuit conducted no inquiry into whether Elbert would have had other expert testimony available if Mr. Kayser's opinions had been struck earlier in the proceeding.

The First, Second, Fourth, Seventh, Tenth and District of Columbia Circuits have not yet taken a position on whether evidence struck following trial must be considered on a renewed motion for judgment. In 1988, the District of Columbia Circuit actually ordered a judgment for defendant after striking the testimony of plaintiff's expert, *see Richardson v. Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988), but apparently it did so without express consideration of the *Midcontinent* line. *Raynor v. Merrell Pharmaceuticals, Inc.*, 104 F.3d 1371, 1373 (D.C. Cir. 1997) ("the issue of whether JNOV can be granted to redress errors of admissibility was neither briefed nor discussed in *Richardson*.") (internal citations omitted). In a later case the D.C. Circuit ruled that, because *Richardson* provided no holding on the issue, the plaintiff had waived reliance on *Midcontinent* by failing to raise it at the trial court level. *Raynor*, 104 F.3d at 1373.

Petitioner respectfully submits that this Court should accept certiorari review to settle the dispute between the circuits. The split is overt and deliberate, and it will not resolve itself.

II. THIS ISSUE IS OF CONSIDERABLE IMPORTANCE IN THE POST-*DAUBERT* WORLD.

The Ninth Circuit's recognition of an absolute right to new trial in every case where evidence in support of

the verdict is adjudged inadmissible after trial or on appeal is not only the subject of a clear split that is unlikely to resolve itself without this Court's guidance, it is also wrong and will have a very costly impact in the post-*Daubert* world. This flat rule will inevitably increase the caseload of the federal courts, increase the costs of resolving disputes, and delay the resolution of claims. The problem will likely arise in many cases, because trial courts have assumed a more activist role as gatekeepers of expert opinion testimony following *Daubert*, and there will likely be many occasions when the decision to admit expert testimony is reconsidered following trial. *Daubert* made trial judges the gatekeepers, but the Ninth Circuit's approach threatens to turn them into revolving door attendants.

The per se rule ignores the fact that in many cases there will be no substitute for evidence which has been properly excluded at trial. For example, a party may be constrained by the scheduling conference order entered in the case from calling witnesses who were not previously identified. *See* Fed. R. Civ. P. 16. Likewise, a decision to exclude an expert that is premised on a substantive determination that the expert's opinions lack scientific validity under *Daubert* cannot be fixed by finding a new expert to express the same opinion. Yet *Schudel* mandates a new trial after upholding a *Daubert* exclusion, and does so without requiring any showing by plaintiffs that they will be able to produce an expert witness who can offer new opinions that overcome the trial court's original objection. To demand a new trial without an assurance of better testimony is a gross waste of judicial resources, ignores Federal Rule 16 and turns *Daubert* on

its head. *Cf. Summers v. Missouri Pac. R.R. Sys.*, 132 F.3d 599, 608 (10th Cir. 1997) (Tacha, J., dissenting) (arguing that the majority decision, which affirmed the trial court's pretrial exclusion of expert testimony for lack of scientific validity but remanded with instructions to allow plaintiff to add new expert, was inconsistent with *Daubert*'s spirit and rationale).

In place of a per se rule, the Third Circuit properly adopted a case-by-case approach giving the district court discretion to determine whether a new trial is warranted when the decision to admit evidence is reconsidered after trial. The district courts generally possess discretion to control the flow of evidence and testimony during trial and to determine whether a request to add new witnesses should be granted. *E.g., Price v. Seydel*, 961 F.2d 1470, 1474 (9th Cir. 1992). Certiorari review would provide an opportunity for this Court to recognize that this discretion extends to post-trial proceedings, and to provide guidance on how it should be exercised.

CONCLUSION

For the reasons set forth herein, Howmedica respectfully requests the petition for certiorari be granted.

Respectfully submitted,

JACQUELINE L.S. EARLE
Counsel of Record
MARGARET JENKINS LEONG
GOODSILL ANDERSON QUINN & STIFEL
1099 Alakea Street, Suite 1800
Honolulu, Hawaii 96813
Ph: (808) 547-5600

Attorneys for Petitioner
Howmedica Inc.

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEORGE ELBERT, *Plaintiff-Appellant,* v. HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc., *Defendant-Appellee.*	No. 96-16249 D.C. No. CV-91-00616-BMK OPINION

Appeal from the United States District Court
for the District of Hawaii
Barry M. Kurren, Magistrate Judge, Presiding

Argued and Submitted
November 5, 1997 - Honolulu, Hawaii

Filed May 8, 1998

Before: Stephen Reinhardt, Edward Leavy and Sidney R. Thomas, Circuit Judges.

Per Curiam Opinion; Concurrence by Judge Reinhardt

COUNSEL

Stanford H. Masui, Honolulu, Hawaii, for the appellant.

Jacqueline Earle, Goodsill, Anderson, Quinn & Stifel, Honolulu, Hawaii, for the appellee.

OPINION

PER CURIAM:

George Elbert appeals from an order granting judgment as a matter of law to Howmedica, Inc., and denying his motion for a new trial. We reverse and remand.

Following a jury verdict, the district court entered judgment of $196,755 for Elbert against Howmedica for damages caused by an allegedly defective prosthetic knee manufactured by Howmedica. In the first appeal of this case, we reversed the judgment in an unpublished opinion because the district court allowed Elbert's unqualified expert to testify. On remand, Howmedica moved "for entry of judgment in its favor on all remaining claims." It cited to Rule 7, Fed. R. Civ. P., which deals with forms of motions. The magistrate judge called it a "novel motion," treated it as a motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50(b), and granted it. The court also denied Elbert's motion for a new trial, holding in relevant part that without the expert testimony the plaintiff could not establish the standard of care required of Howmedica.

The primary question presented by this appeal is whether a trial court, in deciding a Rule 50(b) motion following a remand from an appellate decision requiring exclusion of evidence, may exclude from its decision the evidence erroneously admitted at trial. We recently considered this question in an analogous context and held that when deciding a Rule 50(b) motion following trial, the trial court should not exclude such evidence. Specifically, we wrote in *Schudel v. General Elec. Co.*, 120 F.3d

991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. ___ (1998) that:

> We now hold that when ruling on a Rule 50(b) motion, a district court should not exclude evidence erroneously admitted at trial. The record should be taken as it existed when the trial was closed. This rule promotes certainty: litigants need not supplement conditionally admitted evidence, perhaps, unnecessarily; and district courts need not speculate as to what other evidence might have been offered if the evidence had been excluded at trial. The rule promotes fairness: punishing a litigant for the court's erroneous admission of evidence is unfair; and the remedy of a new trial is available to put both sides on an equal footing. (citation omitted).

Schudel involved the district court's exclusion of evidence during its consideration of a Rule 50(b) motion, after the court thought better of a prior ruling admitting expert testimony. However, the logic applies with equal force to a Rule 50(b) motion made following remand after an appellate ruling that expert testimony was improperly admitted.

Thus, in this case, the trial judge erred in excluding the erroneously admitted evidence when deciding Howmedica's Rule 50(b) motion after remand. Because the Rule 50(b) motion should have been denied, the trial court also erred in denying the plaintiff's motion for a new trial. Although the parties have varied opinions on what may occur in the trial court after remand, none of those issues are before us, and our consideration of those issues would be premature and based on pure conjecture as to what motions the parties might file.

REVERSED AND REMANDED.

REINHARDT, Circuit Judge, concurring in judgment.

I agree that the proper result in this case is to reverse the judgment as a matter of law and to remand for further proceedings. While the majority seems to hold that Rule 50(b) motions on remand should always be denied, I would simply say as a flat rule that litigants may not bring such motions following remand. While my approach may not differ from the majority's from a practical standpoint, I believe it would save litigants and district courts the trouble of filing and adjudicating non-cognizable motions.

Provided it makes a motion for a directed verdict at the close of evidence, a party that loses at trial may under Rule 50(b) "renew its request for judgment as a matter of law by filing a motion no later than 10 days after the entry of judgment." Fed. R. Civ. P. 50(b); *see also Collins v. City of San Diego*, 841 F.2d 337, 342 (9th Cir. 1988) (holding that "[i]f no motion for a directed verdict has been made, a motion for judgment notwithstanding the verdict has no legal effect"). The Advisory Committee Notes explain that "[a] post-trial motion for judgment [notwithstanding the verdict] may be granted only on grounds advanced in the pre-verdict motion." Fed. R. Civ. P. 50(b) advisory committee's notes to 1991 amendment; *see also Murphy v. City of Long Beach*, 914 F.2d 183, 186 (9th Cir. 1990) (same).

As our per curiam opinion makes clear, a 50(b) motion must be based on the *entire* trial record and, in ruling on the motion, the district court must base its

decision on that entire record and cannot take into account the fact that a part of the evidence may have been improperly admitted. Per Curiam Op. at 4551-52; *see also Schudel v. General Elec. Co.*, 120 F.3d 991, 995 (9th Cir. 1997), *cert. denied*, 118 S. Ct. ___ (1998). Unless the district court grants the 50(b) motion or the court of appeals holds that the losing party was entitled to prevail, the party against whom the verdict was rendered cannot obtain a judgment as a matter of law.

I believe that the plain import of this procedural scheme is that a party may not under any circumstances make a Rule 50(b) motion on remand. The reason for this conclusion is simple. As we have just explained, it is the full trial record on which a Rule 50(b) motion must be based. Nothing, therefore, is changed for purposes of such a motion when the court of appeals holds that a portion of the evidence at trial was improperly admitted. Following remand, the district court would be faced with the *identical* question that existed at the time at which, under the Federal Rules, a 50(b) motion must be made – within ten days after the entry of judgment. The losing party at trial must either make its Rule 50(b) motion shortly after the verdict or forfeit its opportunity to do so. If it has made such a motion and lost, there is no point in, or justification for, making it once again on remand. The district court has *already* ruled, and the losing party has either accepted that ruling by not appealing or the court of appeals has concluded that it is not entitled to judgment as a matter of law. If the losing party failed to make a Rule 50(b) motion within the time prescribed by the Federal Rules of Civil Procedure, it has forfeited that

right and there is no reason, let alone provision of the Federal Rules, that would allow its revival on remand.

Because I believe that the district court should not have converted Howmedica's "novel" motion into a 50(b) motion in the first place, I concur in the judgment reversing and remanding for a new trial.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF HAWAII

GEORGE ELBERT, Plaintiff, vs. HOWMEDICA, a Division of PFIZER HOSPITAL PRODUCTS GROUP, INC. Defendant.	CIVIL NO. 91-00616BMK (Filed Jun 24, 1996)

ORDER GRANTING DEFENDANT'S MOTION FOR DISPOSITION OF CASE FOLLOWING REMAND AND DENYING PLAINTIFF'S MOTION FOR NEW TRIAL

The court heard Plaintiff's Motion for New Trial and Defendant's Motion for Disposition of Case Following Remand on December 15, 1995. Stanford H. Masui, Esq. appeared at the hearing on behalf of Plaintiff George Elbert ("Plaintiff" or "Elbert"). Jacqueline Earle, Esq., and Margaret Jenkins Leong, Esq., appeared at the hearing on behalf of Defendant Howmedica, Inc. ("Defendant" or "Howmedica"). After reviewing the motions and the supporting and opposing memoranda, the court GRANTS Defendant's Motion for Disposition of Case Following Remand and DENIES Plaintiff's Motion for New Trial.

BACKGROUND

This is a products liability action which commenced jury trial on August 3, 1993. On August 12, 1993, the jury rendered a verdict in favor of Plaintiff on his claims for

negligence and breach of implied warranty; the jury found Plaintiff Elbert contributorily negligent in causing his injuries. Defendant Howmedica appealed this verdict to the Ninth Circuit Court of Appeals. On June 28, 1995, the Ninth Circuit rendered its decision, affirming in part and reversing in part. *See Elbert v. Howmedica*, Mem. Op. No. 94-15683 (9th Cir. June 28, 1995).

Specifically, the Ninth Circuit reversed the admission of expert testimony by Kenneth Kayser pursuant to Fed. R. Evid. 702. The court held that Kayser presented no evidence to support his qualification in the specific areas to which he testified. The court held that Kayser improperly testified to matters which were "unequivocally outside any area of expertise he might have." Mem. Op. at 3. The court also stated in dicta that Kayser's testimony was crucial to the issue of delamination of Elbert's prosthetic knee (hereinafter sometimes referred to as the "PCA knee"). *Id.* The court further stated that there was strong evidence that Kayser's testimony was prejudicial to Defendant's position in light of the jury finding negligence and breach of implied warranty, despite a finding of no strict liability. *Id.* The Ninth Circuit rejected Defendant's contention that the verdicts were irreconcilable, while allowing that such verdicts did give an indication that Kayser's testimony had a prejudicial impact.

The Ninth Circuit affirmed this court's holding that Elbert's state law claims were not preempted by the Medical Devices Amendments to the Food and Drug Administration regulations, as well as this court's refusal to modify a stipulated protective order protecting Howmedica's confidential documents. Finally, the Ninth Circuit held that the jury's verdict, finding negligent failure

to warn and breach of implied warranty despite a finding of no strict liability, was neither unreasonable nor irreconcilable. The Ninth Circuit then remanded the case for "further proceedings consistent" with these decisions. Mem. Op. at 5.

On October 30, 1995, Elbert filed a Motion for New Trial, pursuant to Fed. R. Civ. P. 59(a), (e), and 60(b). On October 31, 1995, Howmedica filed a Motion for Disposition of Case Following Remand.

STANDARD OF REVIEW

A. Plaintiff's Motion for New Trial

Rule 59 of the Federal Rules of Civil Procedure allows a court to grant a new trial "in an action in which there has been a trial by jury, for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States. . . . " Fed. R. Civ. P. 59(a)(1). Rule 59 likewise allows for amendments of judgment. Fed. R. Civ. P. 59(e). A motion for new trial must be made no later than ten days after entry of the judgment. Fed. R. Civ. P. 59(b). A motion for a new trial or to amend judgment is committed to the sound discretion of the trial court. *See Allied Chemical Corp. v. Daiflon, Inc.*, 449 U.S. 33 (1980) (motion for a new trial); *Metromedia Co. v. Fugazy*, 983 F.2d 350 (2d Cir.) (motion for new trial), *cert. denied*, 508 U.S. 952 (1992); *McCarthy v. Manson*, 714 F.2d 234 (2d Cir. 1983) (motion to amend judgment).

Likewise, motions for relief from judgment pursuant to Fed. R. Civ. P. 60(b) are also committed to the sound discretion of the trial court. *Maraziti v. Thorpe*, 52 F.3d 252, 253 (9th Cir. 1995); *Blair v. California*, 38 F.3d 1514, 1517

(9th Cir. 1994), *cert. denied*, ___ U.S. ___, 115 S. Ct. 1698 (1995). The court may relieve a party from a final judgment when a prior judgment upon which it is based has been reversed or otherwise vacated. Fed. R. Civ. P. 60(b)(5). Such motion must be made within a "reasonable time." Fed. R. Civ. P. 60(b).

B. Defendant's Motion for Disposition Following Remand

This court will review Defendant's Motion for Disposition Following Remand according to the standard for a renewed motion for judgment as a matter of law. Fed. R. Civ. P. 50(b). A judgment as a matter of law pursuant to Rule 50 is proper only when the evidence permits only one reasonable conclusion as to the verdict. *McGonigle v. Combs*, 968 F.2d 810, 816 (9th Cir. 1992), *cert. dismissed sub nom., Casares v. Spendthrift Farm, Inc.*, 506 U.S. 948 (1992). The court must view the evidence in the light most favorable to the nonmoving party and draw all inferences in favor of that party. *Redman v. County of San Diego*, 942 F.2d 1435, 1439 (9th Cir. 1991) (en banc), *cert. denied*, 502 U.S. 1074 (1992). A directed verdict should be granted when the evidence permits only one reasonable conclusion as to the verdict. *Glover v. BIC Corp.*, 6 F.3d 1318, 1330 (9th Cir. 1993). If conflicting inferences may be drawn from the facts, the case must go to the jury. *Id.*

DISCUSSION

Plaintiff requests that this court grant a new trial arguing, without conceding, that if Kayser's testimony was prejudicial, then a new trial is required. Plaintiff also

argues that if the Ninth Circuit determined that, once Kayser's testimony was excluded, there were no facts or evidence sufficient to uphold the jury's verdict, then the Ninth Circuit itself would have disposed of the case, without remanding it to the trial court. Finally, Plaintiff appears to argue that there is sufficient evidence, despite the excluded expert testimony, to warrant a retrial on the issues of negligence and breach of implied warranty.

Howmedica argues, both in its reply to Elbert's Motion and in its own Motion for disposition of Case, that the Ninth Circuit's order of remand does not necessarily mandate a new trial. Howmedica apparently concedes that the Ninth Circuit's silence on the issue left to this court's discretion what type of proceedings are needed to reconcile the jury's verdict and the Ninth Circuit's decision striking Kayser's testimony. Howmedica argues that this court should grant a form of summary judgment, entitled "Disposition of Case Following Remand," to Howmedica based upon Plaintiff's lack of evidence presented at the first trial showing that his injuries were due to any fault or negligence on Howmedica's part; the crux of Defendant's arguments for dispostion [sic] following remand is that, absent Kayser's testimony, there remains no evidentiary basis for finding that Defendant's conduct fell below the applicable standard of care, for that standard of care cannot be established absent expert testimony; and that no finding of unmerchantability could be sustained, absent expert testimony, sufficient for the breach of implied warranty verdict.

A. Procedure Following Remand

Plaintiff contends that "it goes without saying" that the Ninth Circuit would have reversed the trial verdicts if there were no factual or evidentiary basis for them and cites to *Forged Steel Wheel Co. v. Lewellyn* for support. 251 U.S. 511 (1920). *Forged Steel* does not support Plaintiff's proposition. The holding in *Forged Steel* was that it was not error for the appellate court to reverse the trial court judgment where the appeal turned upon only matters of law. *Id.* at 515-16. In this case, the Ninth Circuit was free to review the record of the trial and could have reversed the verdicts; as Defendant correctly notes, the Ninth Circuit was equally free to explicitly order a new trial following remand, as it has done in other cases. 28 U.S.C. § 2106; *Barber v. United States,* 711 F.2d 128 (9th Cir. 1983).

The Ninth Circuit has left it to this court to review the evidentiary record and ascertain the appropriate course to take following remand.

B. Plaintiff's Motion for New Trial

This court will consider Elbert's Motion for New Trial based upon Rule 60, rather than Rule 59, due to the issue of the timeliness of Plaintiff's Motion for New Trial.[1] This court does find that Elbert brought his motion well within the "reasonable" period required for relief from a

---

[1] Although this court set a motions deadline of October 31, 1995, following remand from the Ninth Circuit, it is not clear that this deadline exempts Plaintiff from the ten day deadline under Rule 59.

judgment or order under Fed. R. Civ. P. 60(b), and within the deadline for motions set by the court on July 13, 1995.

Elbert indicates that at a new trial, his negligence case would rely upon the testimony of Dr. Allen Richardson, Defendant's witnesses Stephen Cook, and expert Dr. John Lyons, as well as evidence from Howmedica Director of Polymer Technology Caspar Stark concerning the design and development of the PCA knee and particularly the role of polyethylene wear in the failure of Elbert's PCA knee. (Pl.'s Mem. in Supp. of Mot. for New Trial, at 17.) Likewise, at a new trial, Elbert indicates he would rely upon Dr. Richardson's testimony that Elbert's PCA knee did not live up to his professional expectations, literature prepared by Defendant regarding the useful life of the PCA knee, and statements from Dr. Lyons that failure of a prosthesis within three years fell short of his performance expectations for Elbert's proof of breach of warranty.

C. Defendant's Motion for Disposition of Case Following Remand

Defendant has made a novel motion, a Motion for Disposition of Case Following Remand. Defendant made its initial motion for judgment as a matter of law at the close of Plaintiff's case, which motion was granted as to Plaintiff's claim based upon express warranty and denied in all other respects. (Order Granting in Part and Denying in Part Def. Howmedica's Mot. for J. as a Matter of Law filed August 6, 1993; filed August 25, 1993.) Defendant renewed its motion at the close of all evidence, which renewed motion was likewise denied. At this juncture,

following the Ninth Circuit's ruling that it was error to permit Kayser to testify as an expert witness at trial, this court reviews anew Defendant's motion for judgment as a matter of law. Fed. R. Civ. P. 50(b).

D. Remaining Claims

i. Negligence

Dr. Richardson was Plaintiff's treating physician, the doctor who implanted the PCA knee into Elbert's leg. At trial, Dr. Richardson offered equivocal testimony on what had been the cause of the failure of Elbert's PCA knee. He testified that he could not describe the polyethylene component of the PCA knee as having delaminated. (Transcript of Proceedings (hereinafter "Tr.") 8/3/93 at 171.) Dr. Richardson did offer that he observed the PCA knee to have "destructed, fallen apart and parts of it had come off. . . . " *Id.* at 147. Defendant points out that Dr. Richardson never gave his opinion, to a reasonable medical probability, that Elbert's PCA knee was subject to delamination. (Def.'s Mem. in Opp'n to Pl.'s Mot. at 6.)

In order to render a verdict for Plaintiff upon his negligence claim, the jury was instructed that they had to judge Howmedica's conduct by the standard of care "of a reasonably prudent manufacturer of knee prostheses." (Jury Instruction No. 22.) Defendant points out, that despite Plaintiff's contention to the contrary, none of the witnesses cited by Plaintiff, other than Kayser, testified that the testing of the heat-polished materials in the PCA knee fell below the standard of care. Cook stated that the wear testing performed on the knee was appropriate and adequate. (Tr. 8/11/93 at 13-14.) Plaintiff's witness Roy

Bloebaum did not testify that the tests he performed upon retrievals of failed prostheses would have been appropriate for Howmedica's manufacturing process. Furthermore, Bloebaum testified that it was not a design defect to employ the polyethylene material used in the PCA knee. (Video Dep. of Bloebaum 7/24/93, at 67; read into Tr. 8/4/93.) The evidence adduced at trial from Dr. Lyons indicated that Howmedica was aware of some design risks, risks which were no greater than in other products available at the time; Dr. Lyons testified that Howmedica was taking measures to optimize the PCA knee by resolving competing design concerns. (Tr. 8/9/93 at 76).

Finally, testimony from Howmedica's Stark that the polyethylene components in the PCA knee contributed to its failure, as well as the Polyethylene Awareness Series indication that a thicker component was appropriate in a knee prosthesis does not establish that Howmedica's conduct fell below the relevant standard of care. Although the polyethylene component of the PCA knee may be described as the "weak link" in the device, Plaintiff's witness Bloebaum (and others) acknowledged that it was the only material that was available at the time for such purpose. (Video Dep. of Bloebaum 7/24/93, at 67; read into Tr. 8/4/93.) Furthermore, the Polyethylene Awareness Series was not available until years subsequent to implantation of the PCA knee in Elbert; it was Elbert's physician Dr. Richardson who testified that at the time of implantation of Elbert's knee, a thinner prosthetic implant would have been preferred in order to minimize

bone loss, however, henceforth he would give consideration to a thicker component in order to reduce implant wear. (Tr. 8/3/93 at 193.)

In order for Plaintiff to prevail on a theory of negligent failure to warn, the jury had to find that Defendant failed to exercise ordinary care to give warning in the face of knowledge that the user of the product would not recognize its dangerous condition. In this case where a physican [sic] selected the product to be implanted, the adequacy of warnings is measured by the warnings given to the health care provider and the "learned intermediary" doctrine applies. *See Craft v. Peebles*, 78 Haw. 287, 304-05, 893 P.2d 138, 155-156 (1995).

Assuming that Defendant had a continuing duty to warn based upon knowledge acquired several years subsequent to the implantation of Elbert's PCA knee, there was no evidence at trial that failure to provide additional warnings to Elbert's treating physician was a cause of harm to Elbert. If Dr. Richardson were aware of the risk of bone loss from synovitis, an inadequacy in Howmedica's warning in light of acquired knowledge would not be a proximiate [sic] cause of Elbert's alleged injury. *Plummer v. Lederle Laboratories*, 819 F.2d 349, 358-59 (2d Cir.), *cert. denied*, 484 U.S. 898 (1987). Even if Dr. Richardson were not aware of the risk of bone loss due to synovitis, no evidence was introduced to indicate that Elbert's treatment would have been different during the relevant period or that the implant would have been removed; as of February, 1990, according to Dr. Richardson's testimony, Elbert's knee prosthesis was "working perfectly." (Tr. 8/3/93 at 165.)

Although the finding of negligence is normally within the province of the trier of fact, where the facts are such that an ordinary person would not have personal knowledge from which to judge whether the conduct complained of was in breach of duty, or the causation of the injury, expert evidence is required to prove negligence. *Compare Brown v. Clark Equipment Co.*, 62 Haw. 530, 537 (1980) (expert testimony not required where the issues were within the common knowledge of jurors, issue of negligence in design of construction vehicle with blind spot, without mirrors or without advising purchasers that mirrors available for installation); *Cozine v. Hawaiian Catamaran, Ltd.*, 49 Haw. 77, 83, 412 P.2d 669, 676 (1966) ("It requires no expert testimony to enable a jury to infer that in the ordinary course of event [sic] and if due care is used the mast of an excursion boat does not snap off. . . . "). Expert testimony is routinely required to establish the standard of care in professional malpractice cases, save for those factual circumstances which fall within the ordinary understanding of jurors. W. Page Keeton, et al., Prosser and Keeton on the Law of Torts, § 32 at 189 (5th ed. 1984) ("Where the matter is regarded as within the common knowledge of laymen, as where a surgeon saws off the wrong leg, or there is injury to a part of the body not within the operative field, it has been held that the jury may infer negligence without the aid of any expert.")

The jury was instructed that the duty of care a manufacturer owes a user "is dependent upon the foreseeable risk of harm to potential users in light of then current scientific or medical knowledge and discoveries." (Jury Instruction No. 23.) Without Kayser's testimony, there

was no expert testimony to establish the standard of "then current scientific or medical knowledge and discoveries," whether Howmedica breached its duty as a manufacturer by failing to meet its duty, or, indeed, whether a failure by Howmedica to use ordinary care was the cause of Elbert's injuries. It is not the case here that a prosthetic knee will not fail absent a defect. Indeed, the jury explicitly found that Elbert was partially at fault for the failure of his knee.

Elbert's reliance upon Drs. Richardson and Lyons, Cook and Stark, as effective support of the jury's verdict for negligence is ill founded. Certainly these witnesses, taken together, did support Plaintiff's contention that the PCA knee failed sooner than expected, that there existed certain concerns that the polyethylene was the "weak link" in the device, that the design of the PCA knee had certain drawbacks. However, this evidence fails to establish the relevant standard of care or show that Howmedica breached their duty.

This court finds that the design, manufacture, testing, and development of replacement knee prostheses products is well beyond the knowledge of the lay juror; what function is to be achieved, by what methods, and at what relative risk cannot be said to be within the understanding of the individuals selected for the jury pool. Furthermore, as said by the Ninth Circuit, the PCA knee was "unavoidably imperfect, as are all man-made joints." Mem. Op. at 4. That being the case, this court holds that expert testimony is required to establish the relevant standard of care for reasonably prudent manufacturer of knee prostheses in order for the jury to determine if it was breached, as well as determine if any such breach

caused Elbert's injuries. The absence of such testimony after remand requires that the court enter judgment in favor of Defendant on Plaintiff's claim for negligence.

In ruling on Defendant's motion for judgment as a matter of law at trial, this court explained that:

> Now, on the negligence issues, this is a closer call in my judgment. But I think Mr. Kayser's testimony, also, in my view, creates a jury issue as to negligent manufacturing processes. . . . [H]is testimony concerning how he thought the practices of defendant in this case varied from those standard practices that he is aware of does, in my view, create a jury issue.

(Tr. 8/10/93 at 662.) Whereas Kayser's testimony is no longer part of this case, this court now concludes that the remaining evidence does not give rise to a jury issue in negligence. Rather, loss of Kayser's testimony is fatal to Plaintiff's negligence claim.

ii. Breach of Implied Warranty

Under Hawaii law, the Plaintiff in product liability action for breach of implied warranty for personal injury is required to show that the product was "unmerchantable sufficient to avoid summary judgment on the issue of defectiveness in a tort strict products liability suit." *Larsen v. Pacesetter Systems, Inc.*, 74 Haw. 17, 22 (1992). In accordance with such standard, the jury was instructed that in order to find for Plaintiff on a breach of implied warranty theory, Plaintiff had to prove by a preponderance of the evidence that "[P]laintiff's knee prosthesis was not fit for the ordinary purposes for which knee

prostheses are used. . . . " (Jury Instruction No. 33.) Whereas the only evidence that the PCA knee was not fit for the ordinary purposes for which it was used came from Kayser, Plaintiff has a fatal defect of his proof of a breach of implied warranty. Despite Dr. Richardson's testimony that he believed the knee should have lasted longer, and Dr. Bloebaum's testimony that there were tests which were possible to have been administered, no competent expert evidence remains in Plaintiff's case from which the jury could have concluded that the PCA knee device was not fit for ordinary purposes as a knee prosthesis. The evidence which does remain is that the PCA knee functioned well for Elbert for a period of years and that Elbert himself "pushed his joint beyond its mechanical endurance." Mem. Op. at 4.

Whereas Kayser's testimony is no longer part of this case, this court concludes that the remaining evidence does not give rise to a jury issue in breach of implied warranty.

CONCLUSION

This court finds that absent Kayser's testimony, there was insufficient evidence of negligence or breach of implied warranty by Howmedica to support the jury verdict returned in favor of Plaintiff. Absent such evidence, this court must rule in Howmedica's favor, as a matter of law, on Plaintiff's claims for negligence and breach of implied warranty.

For the reasons stated above, the court GRANTS Defendant's Motion for Disposition of Case Upon Remand and DENIES Plaintiff's Motion for New Trial. It

is ORDERED that judgment be entered in Defendant's favor on Plaintiff's remaining causes of action.

IT IS SO ORDERED.

Dated: Honolulu, Hawaii, June 21, 1996.

/s/ Barry M. Kurren
Barry M. Kurren
United States
Magistrate Judge

NOT FOR PUBLICATION
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

GEORGE ELBERT, Plaintiff-Appellant, vs. HOWMEDICA, INC., a Division of PFIZER HOSPITAL PRODUCTS GROUP, INC., Defendant-Appellee.	No. 94-15683 D.C. No. CV-91-00616-HMK MEMORANDUM* (Filed Jun. 28, 1995)

Appeal from the United States District Court
for the District of Hawaii
Barry M. Kurren, Magistrate Judge, Presiding

Argued and Submitted May 3, 1995
Honolulu, Hawaii

Before: PREGERSON, KOZINSKI, and HAWKINS, Circuit Judges.

Following a jury verdict, the district court entered judgment of $196,775 for George Elbert against Howmedica, Inc. for damages caused by an allegedly defective prosthetic knee ("PCA knee") manufactured by Howmedica. We have jurisdiction under 28 U.S.C. § 1332 and 28 U.S.C. § 1291.

---

*This disposition is not appropriate for publication and may not be cited to or by the courts of this circuit except as provided by 9th Cir. R. 36-3.

We affirm the decisions denying preemption, reconciling the jury's verdicts and protecting Howmedica's confidential documents.

We conclude that the court erred in admitting certain expert testimony, and on that basis we reverse and remand.

The jury found that Howmedica was negligent and breached an implied warranty in its manufacture and sale of the PCA knee. But the jury found no strict liability.

Howmedica appeals the district court's verdict on three grounds: (1) the district court erred in admitting Kenneth Kayser's testimony regarding the PCA knee deterioration (delamination) and Howmedica's breach of due care in the manufacture and testing of the PCA knee; (2) Elbert's state law claims alleging negligence and breach of implied warranty were preempted by the Medical Device Amendments ("MDA") to the Food and Drug Administration regulations; and (3) the jury's findings of negligence and breach of implied warranty are not reconcilable with its finding against strict liability.

Elbert appeals the district court's denial of his motion to lift the pre-trial stipulated order protecting Howmedica's confidential documents. Elbert does not appeal the finding of no strict liability. The issue of strict liability, therefore, is not before the Court.

I

Elbert's expert in this case, Kenneth Kayser, was an electrical engineer who admitted to having no training or

familiarity with prosthetic knee joints or their components prior to his enlistment as an expert witness. Having never before seen a PCA knee, Kayser drew his conclusions regarding Howmedica's manufacturing process and duty to test only from reviewing extracts of articles others had published. Kayser presented no evidence of his experience or qualifications regarding the specific subject areas in which he offered testimony. Yet Kayser's testimony was crucial to the issue of delamination, the critical flaw alleged in the PCA knee. Kayser was the only witness who offered testimony asserting that Howmedica could have known and should have known its PCA knee would delaminate and thereby produce Elbert's injury.

The jury's award against Howmedica for negligence and breach of warranty, despite its finding of no strict liability, is strong evidence that Kayser's testimony was prejudicial. We find that the district court abused its discretion under Fed. R. Evid. 702 in permitting the jury to hear Kayser's opinions as to subject areas which were unequivocally outside any area of expertise he might have.

Accordingly, we reverse the district court's admission of Kayser's expert testimony.

II

The district court properly considered the scope of the MDA's preemption clause in determining that Elbert's state law claims were not preempted by the MDA. 21 U.S.C. § 360k. The FDA clarified the MDA's preemption clause in its regulations: "State or local requirements are preempted only when the Food and Drug Administration

has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d) (1992). The FDA did not establish specific standards or requirements as to the class II device PCA knee implanted into Elbert with *bone cement* in 1986. *See* 21 C.F.R. § 888.3560. Thus we affirm the district court's finding that neither the MDA nor FDA regulations preempted Elbert's state tort actions.

III

The jury's verdicts were neither unreasonable nor irreconcilable. Negligent failure to warn and breach of implied warranty are causes of action distinct from an action for strict product liability.

The jury had a number of reasons to not find Howmedica strictly liable for the PCA knee failure. First, Howmedica's product was not abnormally hazardous, since it functioned well for Elbert over a period of years. Second, the PCA knee was unavoidably imperfect, as are all man-made joints. Third, the need for the PCA knee replacement outweighed the harm from the replacement's failure. Finally, Mr. Elbert was held to be partially at fault for pushing his joint beyond its mechanical endurance.

IV

Howmedica reasonably relied on the integrity of the court's protective order when it disclosed information under the initial discovery agreements. The district court did not abuse its discretion in refusing Elbert's request to

modify a stipulated protective order for the apparent purpose of facilitating future actions against Howmedica.

We affirm the district court's denial of Elbert's motion to lift the protective order.

V

The judgment of the district court is AFFIRMED in part and REVERSED in part. We remand this case for further proceedings consistent with the views set forth above.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NO. 96-16249
CT/AG#: CV-91-00616-BMK

GEORGE ELBERT

Plaintiff-Appellant

v.

HOWMEDICA, INC., a Division of Pfizer Hospital Products Group, Inc.

Defendant-Appellee

JUDGMENT

(Filed Jun. 3, 1998)

APPEAL FROM the United States District Court for the District of Hawaii (Honolulu).

THIS CAUSE came on to be heard on the Transcript of the Record from the United States District Court for the District of Hawaii (Honolulu) and was duly submitted.

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court, that the judgment of the said District Court in this cause be, and hereby is reversed and remanded.

Filed and entered: May 8, 1998

FILED
SEP 8 1998
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 98-245

In The

Supreme Court of the United States

October Term, 1997

HOWMEDICA, INC., A Division of Pfizer Hospital Products Group, Inc.,

Petitioner,

vs.

GEORGE E. ELBERT,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Ninth Circuit

RESPONDENT'S BRIEF IN OPPOSITION

Of Counsel:

TAKAHASHI, MASUI & VASCONCELLOS
Attorneys at Law

HERBERT R. TAKAHASHI #1011-0
STANFORD H. MASUI #1801-0
Counsel of Record
DANNY J. VASCONCELLOS #4617-0
REBECCA L. COVERT #6031-0
547 Halekauwila Street, Room 206
Honolulu, Hawaii 96813
Telephone Number: (808) 526-3003

Attorneys for Respondent

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

18 pp

QUESTION PRESENTED

Whether or not there are compelling reasons to reverse the Ninth Circuit on a procedural issue which has not been directly decided by any other Circuit Court of Appeals, and is consistent with all Circuits on an analogous issue.

PARTIES TO THE PROCEEDING

Petitioner, Howmedica, Inc., describes itself as a wholly-owned subsidiary of Pfizer Inc.

Respondent George E. Elbert is an individual Plaintiff below.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

PARTIES TO THE PROCEEDING ii

I. INTRODUCTION 1

II. STATEMENT OF THE CASE 1

A. NATURE OF THE CASE AND PROCEEDINGS 1

B. STATEMENT OF THE FACTS 2

C. PROCEEDINGS ON REMAND 4

III. ARGUMENT 5

A. NO COMPELLING REASON HAS BEEN PRESENTED REQUIRING REVIEW BY THE UNITED STATES SUPREME COURT 5

B. THE COURTS OF APPEALS ARE NOT IN CONFLICT, SO AS TO REQUIRE THE INTERVENTION OF THE SUPREME COURT 6

C. ALL OTHER CIRCUITS ARE IN AGREEMENT WITH THE RULING OF THE NINTH CIRCUIT ON THE ANALOGOUS SITUATION 10

IV. CONCLUSION 11

TABLE OF AUTHORITIES

Page

CASES

Aloe Coal Co. v. Clarke Equipment Co., 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987) 8

Daubert v. Merrell Dow Pharmaceutical, Inc., 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) ...1, 3

Douglas v. Eaten Corp., 956 F.2d 1339 (6th Cir. 1992) 10

Jackson v. Pleasant Grove Health Care Ctr., 980 F.2d 692 (11th Cir. 1983) 10

Lightening Lube, Inc. v. Witco Corp., 4 F.3d 1153 (3d Cir. 1993) 8, 10

Lippay v. Christos, 996 F.2d 1490 (3d Cir. 1993) 9

Mid Continent Broadcasting Co. v. North Cent. Airlines, Inc., 471 F.2d 357 (8th Cir. 1973) 11

Montgomery Ward & Co. v. Duncan, 311 U.S. 243, 61 S. Ct. 189, 84 L. Ed. 147 (1940) 9

NLRB v. Pittsburgh S.S. Co., 340 U.S. 498, 71 S. Ct. 453, 95 L. Ed. 479 (1951) 6

Rice v. Sioux City Memorial Park Cemetery, Inc., 349 U.S. 70, 75 S. Ct. 614, 99 L. Ed. 897 (1955).....5, 6

Schudel v. General Electric Company, 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S. Ct. ___ (1998) 5, 6, 7, 11

Sumitomo Bank v. Product Promotion, Inc., 717 F.2d 215 (5th Cir. 1983) 11

STATUTES AND RULES

Sup. Ct. R. 10 5

Sup. Ct. R. 10.1 5

TABLE OF AUTHORITIES – Continued

Page

Federal Rules of Civil Procedure, Rule 7 ..... 2, 4
Rule 50(b) 4, 6, 7, 11
Rule 56 7
Rule 59(a)(e) 2
Rule 60(b) 2
Federal Rules of Evidence, Rule 702 ..... 2, 3, 6

I.
INTRODUCTION

Petitioner Howmedica, Inc., Petition for Writ of Certiorari to this court incorrectly describes the issue involved as a "direct conflict" among other Circuits, by misconstruing the procedural history of this case, in order to obtain Certiorari by this Supreme Court.

The decision of the Ninth Circuit Court involves a specific procedural posture not directly addressed by any other Circuit Court of Appeals, as far as is known to counsel.

Neither does the case involve an issue under *Daubert v. Merrell Dow Pharmaceutical, Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993), hence poses no "threat" to the decision of this court.

II.
STATEMENT OF THE CASE

A. NATURE OF THE CASE AND PROCEEDINGS.

Plaintiff George Elbert filed this product liability case concerning a defective artificial knee prosthesis, manufactured by Defendant Howmedica, Inc., and marketed as the PCA (Porous-Coated Anatomic) Total Knee System.

A jury trial was held beginning August 3, 1993, in the District Court of Hawaii, with the jury rendering a verdict in favor of Plaintiff George Elbert in the amount of $196,775.00 on Plaintiff's claims for negligence and breach of implied warranty. Plaintiff Elbert was also found contributorily negligent, by 15%.

Howmedica appealed the verdict to the Ninth Circuit Court of Appeals, and on June 28, 1995, the Ninth Circuit Court of Appeals rendered its decision, affirming in part and reversing in part. *Elbert v. Howmedica,* Memorandum Opinion 94-15683 (9th Cir. 6/28/95).

The Ninth Circuit reversed the admission of expert testimony by Kenneth Kayser, an engineer pursuant to Rule 702 Federal Rules of Evidence.

The Memorandum Opinion remanded the case for "proceedings consistent" with the Decision.

On October 30, 1995, Elbert filed a Motion for a New Trial pursuant to Rule 59(a)(e), and 60(b) F.R.C.P. On October 31, 1995, Howmedica filed a counter Motion for Disposition of Case Following Remand, citing only F.R.C.P. 7, but no substantive rule.

B. STATEMENT OF THE FACTS

Plaintiff Elbert's case proceeded on several theories of both strict liability, express and implied breach of warranty, and negligence, based on negligent design and manufacture based upon the following:

a. Excess stress (design)

b. Thickness of plastic insert portion of the prosthesis (design).

c. Heat pressing (manufacturing process); Plaintiff alleged that Howmedica failed to properly test, or apply proper testing procedures.

In addition to the testimony of engineer Kenneth Kayser, the testimony of a well-known and a high-

respected treating orthopedic surgeon, Alan Richardson, M.D., was presented on the issue of causation. Additionally, admissions of Howmedica witnesses relating to reports of unusual and unacceptable degradation of polyethylene components received by Howmedica President, James Barbarito was presented. Inculpatory admissions were testified to by the Director of Polymer Technology, Mr. Casper Stark with regard to concerns about problems related to the degradation of the polytheylene component.

An independent research scientist, Roy Bloebaum, Ph.D., employed by the Division of Orthopedic Surgery for the Veteran's Medical Center in Salt Lake City, was also presented, establishing his observation that 52% of the PCA's had delaminated, leading to cracking and deterioration. Dr. Bloebaum's testimony established manufacturing tests his research group conducted, which were never performed by Howmedica as testified by its witnesses.

The testimony of Defense experts conceded that the design of the PCA contributed to the failure of the plastic in this case.

Additionally studies by independent groups, as well as Howmedica, Inc., in house-studies confirmed exceedingly high failure rates for the PCA.

The Ninth Circuit Court, clearly recognizing that the issue of scientific validity raised in *Daubert v. Merrell Dow, supra*, was not involved, ruled on the bases of Federal Rule of Evidence 702, that witness Kenneth Kayser was unqualified, holding specifically that the testimony was

"prejudicial" (p. 5, Howmedica's Petition for Writ of Certiorari).

C. PROCEEDINGS ON REMAND

Howmedica's motion below, cited no rule of procedure, other than Rule 7 Federal Rules of Civil Procedure, hence, the Magistrate Judge treated the motion as a "noval" motion, and utilized the standards under Rule 50(b).

No issue was raised by either side with respect to naming of additional witnesses, additional discovery, or related motions with respect to a new trial, and such motions were not at issue at the court below, pending the disposition of the initial motions to the court.

Additionally, documents were produced during trial, for which Plaintiff Elbert filed a Motion for Sanctions, which was denied; however the late-produced documents could have provided the bases for additional motions with respect to additional discovery if a new trial had been granted.

It was the Plaintiff's contention at oral arguments that Howmedica's motion and the court's disposition below was procedurally defective, for the reason that a 50(b) motion could only be had after a trial, and consideration based upon an abridged version of the previous trial prior to appellate remand was improper.

The Petition of Howmedica has misconstrued the Ninth Circuit Opinion, which clearly states the issue as "whether a trial court, in deciding a Rule 50(b) motion

following a remand from an Appellate decision requiring exclusion of evidence, may exclude from its decision the evidence erroneously admitted at trial." The court specifically remarked that it was considering this issue in an "analogous context," citing *Schudel v. General Electric Company,* 120 F.3d 991, 995 (9th Cir. 1997), *cert. denied,* 118 S. Ct. ___ (1998) (App. 2. Petition for Writ of Certiorari).

III.

ARGUMENT

A. NO COMPELLING REASON HAS BEEN PRESENTED REQUIRING REVIEW BY THE UNITED STATES SUPREME COURT

Rule 10 of the Rules of the United States Supreme Court expressly states:

> Review on a writ of certiorari is not a matter or right, but of judicial discretion. A petition for writ of certiorari will be granted only for compelling reasons. . . . the reasons the court considers:
>
> a. A United States Court of Appeals has entered a decision in conflict with a decision of another United States Court of Appeals on the same important matter; . . .

The prior Supreme Court Rule 10 required that Certiorari be granted "only when there were special and important reasons" Supreme Court Rule 10.1. Hence, under the prior Supreme Court Rule problems that are merely academic, or episodic do not constitute a special and important reason. *Rice v. Sioux City Memorial Park Cemetery, Inc.,* 349 U.S. 70, 75 S. Ct. 614, 99 L. Ed. 897 (1955). Hence, this court has granted Certiorari only in

cases involving principles which are important to the public as distinguished from the parties involved. *NLRB v. Pittsburgh S.S. Co.*, 340 U.S. 498, 71 S. Ct. 453, 95 L. Ed. 479 (1951); *Rice v. Sioux City Memorial Park Cemetery, supra.*

B. THE COURTS OF APPEALS ARE NOT IN CONFLICT, SO AS TO REQUIRE THE INTERVENTION OF THE SUPREME COURT

1. The Ninth Circuit properly decided a novel issue that a Rule 50(b) motion decided after an appellate remand, by analogy to similar cases under Rule 50(b) Federal Rule of Civil Procedure.

The Ninth Circuit Court in rendering its opinion below, explicitly stated that its decision was based upon the analogous situation, in which Rule 50(b) motion was made *following a trial,* the court should not exclude from consideration previously admitted evidence, which it subsequently decides was erroneously admitted. The case of *Schudel v. General Electric Co.*, 120 F.3d 991, 995 (9th Cir. 1997), involved that District Court's exclusion of evidence during a consideration of a Rule 50(b) motion, *following a trial.* The court had reconsidered its prior ruling admitting expert testimony.

In the present case, the court had previously ruled, admitting the testimony of Kenneth Kayser, on the basis of Rule 702 Federal Rules of Evidence, was reversed by the Ninth Circuit Court of Appeal, which expressly ruled that the admission of Kayser's testimony was prejudicial.

The procedural posture of the present case thus differs significantly from the cases cited pro and con on the issue by Petitioner, Howmedica, Inc. The logic of the Ninth Circuit Court in *Schudel, supra*, applies with greater force to a situation whereby an appellate court has remanded a case following an appeal. The successful Plaintiff below finds his case in an entirely different evidentiary *and procedural* posture, since he is bound by evidentiary rulings, and, possibly, by the previous jury verdict, limited to certain theories. (No rulings have been made on this in the present case).

Procedurally, there is no trial record upon remand to rely upon or to evaluate for purposes of 50(b) motion. In this connection, the dissent of Circuit Judge Reinhardt is pertinent, that it is a "full trial record on which a 50(b) motion must be based" (Howmedica's Appendix, 5).

Hence, in the procedural posture of this case, because there was no trial record from which to judge the motion, the Magistrate's ruling was clearly erroneous, as well as contradictory, since the Magistrate below had previously ruled at the first trial, that there was sufficient evidence (including Kenneth Kayser's testimony, to submit to a jury). Finally, the plain terms of 50(b) requires that such motions for verdict must be made "no later than 10 days after entry of judgment". Since obviously there was no judgment, such a motion, cannot even be procedurally considered.

When looked at objectively, Howmedica sought to avoid the evidentiary standards of a Rule 56 Motion for Summary Judgment, as well as a Motion for Judgment as a Matter of Law under Rule 50, by not citing any rule of

Federal Procedure to apply. Thus, the Ninth Circuit correctly compared the posture of the case to one in which a Motion for Judgment as a matter of law was made *after trial*, and those cases interpreting the analogous situation.

Additionally, this case differs from other cases cited by Howmedica attempting to ignore other evidence of causation, in this case, and standard of care presented below at the first, and only trial of this matter. Unlike other cases cited by the Courts of Appeals, Plaintiff Elbert cited other experts, and documentary evidence relating to the standard of care and causation. Additionally, the issue of further discovery was never addressed, since presumably, once there was a remand, and had Magistrate initially denied Howmedica's motion, such discovery motions, including the naming of new experts, could have been considered properly. However, Elbert's case never proceeded to a point where such matters could have been adjudicated.

2. The Circuit Court of Appeals are in agreement that the alternative remedy for the introduction of prejudicial evidence is a new trial.

Howmedica cites the Third Circuit of Appeal cases of *Aloe Coal Co. v. Clarke Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L. Ed. 2d 111 (1987), and *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993), in support of its proposition that there is a conflict among the Circuits related to this issue. However, the *Aloe Coal Co.* decision is conceded by Howmedica to be dictum only. The *Lightening Lube, Inc.* case, *supra*, did consider the issue, however, as pointed out above, not in the same procedural posture as the present

case, involving a renewed motion for judgment after a full trial, and not after a remand following an appellate decision.

The Third Circuit relied on the case of *Lippay v. Christos*, 996 F.2d 1490, 1501 (3d Cir. 1993). The court in *Lightening Lube, Inc.*, considered that the Supreme Court of the Untied States in dicta, stated that the District Court erred in admitting or excluding evidence which should not be considered in a Motion for Judgment, citing *Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 249, 61 S. Ct. 189, 194, 84 L. Ed. 147 (1940).

The Third Circuit Court expressly recognized those instances whereby it would be clearly inappropriate for District Court to rely on evidentiary error in construing a Motion for Judgment:

> There is a difference in determining whether evidence should be excluded on a Motion for Judgment as a matter of law and deciding whether a record contains sufficient evidence to sustain a verdict. For example, a litigant moving for judgment as a matter of law may argue as a reason for granting its motion that certain of evidence was admitted erroneously because it was prejudicial. It is possible that even excluding such evidence, the jury had a sufficient reason to find against the movant, but the admission of the additional evidence so inflamed it as to affect its deliberation. This might be the case, for example, with bad character evidence introduced pursuant to Federal Rules of Evidence 608. *In such a case it clearly would be inappropriate for the District Court to rely on this evidentiary error in granting the Motion for*

> *Judgment because the issue of harmful error is distinct from the issue of the sufficiency of the evidence,* . . . 4 F.3d at 1199, fn. 26.

All that *Lightening Lube, Inc., supra,* stands for, is that in the Third Circuit, there are limited instances in which the federal court may determine a Motion for Judgment following a trial by considering inadmissible evidence. Hence, the Third Circuit cases, are in fact, consistent with the rulings of other Circuits on this issue, but qualifying the rule of other Circuits. Additionally, the *Lightening Lube, Inc., supra,* recognized that a flat, across-the-board rule could lead to "an unjust result where a litigant actually tendered additional evidence, which the District Court excluded on the ground that it was cumulative".

Howmedica concedes in this case that there were procedural rulings, limiting expert witnesses on the issue of liability and/or causation, which could have been presented by Respondent. Although the District Magistrate's ruling was not based on cumulativeness, the situation is precisely the type of situation whereby the Third Circuit could find that "fairness would dictate that the District Court consider entire trial record in ruling on a motion for judgment", *Lightening Lube, Inc. v. Witco Corp., supra,* 4 F.3d 1200.

C. ALL OTHER CIRCUITS ARE IN AGREEMENT WITH THE RULING OF THE NINTH CIRCUIT ON THE ANALOGOUS SITUATION

Howmedica acknowledges that the Eleventh Circuit, in the case of *Jackson v. Pleasant Grove Health Care Ctr.,* 980 F.2d 692 (11th Cir. 1983), and the Sixth Circuit *Douglas v.*

Eaten Corp., 956 F.2d 1339 (6th Cir. 1992), have supported the Ninth Circuit approach. Likewise, the Fifth Circuit in the case of *Sumitomo Bank v. Product Promotion, Inc.*, 717 F.2d 215, 218 (5th Cir. 1983), and the Eighth Circuit in the case of *Mid Continent Broadcasting Co. v. North Cent. Airlines, Inc.*, 471 F.2d 357, 358-59 (8th Cir. 1973), are in harmony with the ruling of *Schudel v. General Electric Co., supra.*

Hence, Howmedica has framed the issue in such a way as to misstate the ruling of the Ninth Circuit, and to mis-characterize the ruling as in conflict with that of the Third Circuit, which is not the case.

IV.

CONCLUSION

The Supreme Court of the United States has adopted the limiting rule of requiring a "compelling reason" to accept Certiorari.

The ruling of the ninth Circuit court is on a distinct procedural issue which has not been reviewed previously by other Circuits.

The analogous situation presented of a Rule 50(b) motion following a full trial, and requiring a court to review the full trial record, including previously admitted evidence, is in harmony with all of the Circuit Courts of

Appeals that have ruled on the issue, and the Supreme Court need not exercise Certiorari.

Respectfully submitted,

Of Counsel:
TAKAHASHI, MASUI & VASCONCELLOS
Attorneys at Law
HERBERT R. TAKAHASHI #1011-0
STANFORD H. MASUI #1801-0
Counsel of Record
DANNY J. VASCONCELLOS #4617-0
REBECCA L. COVERT #6031-0
547 Halekauwila Street, Room 206
Honolulou, Hawaii 96813
Telephone Number:
(808) 526-3003

Attorneys for Respondent

(3)

Supreme Court, U.S.
FILED
SEP 8 1998
OFFICE OF THE CLERK

No. 98-245

In The

Supreme Court of the United States

OCTOBER TERM, 1998

HOWMEDICA, INC., A DIVISION OF
PFIZER HOSPITAL PRODUCTS GROUP, INC.,

Petitioner,

v.

GEORGE E. ELBERT,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

Of Counsel:

Russel A. Bantham
Marjorie E. Powell
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

Bruce N. Kuhlik
Counsel of Record
Theodore Voorhees, Jr.
Robert A. Long, Jr.
Gail H. Javitt
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-6000

September 8, 1998

Counsel for Amicus Curiae

22pp

In The

Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-245

HOWMEDICA, INC., A DIVISION OF
PFIZER HOSPITAL PRODUCTS GROUP, INC.,

Petitioner,

v.

GEORGE E. ELBERT,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MOTION FOR LEAVE TO FILE BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

The Pharmaceutical Research and Manufacturers of America (PhRMA) hereby seeks leave pursuant to this Court's Rule 37.2 to file the attached brief *amicus curiae* in support of Petitioner Howmedica, Inc. Petitioner has consented to the filing of this brief. Respondent's counsel has not responded to repeated requests for consent, but an assistant to

Respondent's counsel has stated orally that Respondent does not consent to the filing of this brief.[1]

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies invest nearly $ 21 billion annually in discovering and developing new medicines, and are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives.

PhRMA frequently participates as *amicus curiae* in judicial proceedings involving issues of concern to the pharmaceutical industry. PhRMA takes particular interest in cases that concern the standards for admitting scientific testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and submitted briefs *amicus curiae* in both *Daubert*[2] and in *General Electric Co. v. Joiner*, 118 S.Ct. 512 (1997) (holding that trial courts' evidentiary determinations under *Daubert* should be accorded significant deference).

The instant case presents the questions whether expert scientific testimony determined to be inadmissible after trial must be considered by the trial court in reviewing a motion made under Fed. R. Civ. P. 50(b), and whether the trial court must always conduct a new trial under such circumstances, even if no competent scientific evidence supporting an essential element of a plaintiff's claim remains for a jury to consider. Since the product liability claims that are brought against pharmaceutical companies typically require expert

---

[1] Petitioner's letter of consent has been filed with the Clerk of the Court.

[2] The brief was submitted by PhRMA's predecessor, the Pharmaceutical Manufacturers Association.

scientific testimony, the pharmaceutical industry has a substantial interest in ensuring the proper application of *Daubert*. If evidence not meeting *Daubert*'s requirements is incorrectly admitted at trial, it is important to the pharmaceutical industry that the trial court not be required to consider the evidence under Rule 50(b), and that the trial court have discretion to resolve the case in a just and efficient manner.

PhRMA believes that its participation as *amicus curiae* will provide the Court with a broader perspective on the importance to the pharmaceutical industry of protecting the trial court's post-trial discretion under *Daubert*. Accordingly, PhRMA respectfully seeks the Court's leave to file the attached brief supporting Petitioner.

Respectfully submitted,

Of Counsel:

Russel A. Bantham
Marjorie E. Powell
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

Bruce N. Kuhlik
Counsel of Record
Theodore Voorhees, Jr.
Robert A. Long, Jr.
Gail H. Javitt
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-6000

September 8, 1998

Counsel for Amicus Curiae

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES iii

INTEREST OF THE *AMICUS CURIAE* 2

INTRODUCTION AND SUMMARY 3

REASONS FOR GRANTING THE PETITION 4

I. THE NINTH CIRCUIT'S INTERPRETATION OF RULE 50(b) CONFLICTS WITH DECISIONS OF THE THIRD CIRCUIT AND UNDERMINES THIS COURT'S DECISION IN *DAUBERT* 4

A. The Ninth Circuit's Decision Misinterprets Rule 50(b) And Conflicts With Decisions of the Third Circuit 4

B. The Ninth Circuit's Decision Undermines the Principles of *Daubert* 6

II. PHARMACEUTICAL PRODUCT LIABILITY CASES ILLUSTRATE THE IMPORTANCE OF GRANTING COURTS APPROPRIATE POST-TRIAL DISCRETION TO APPLY THE PRINCIPLES OF *DAUBERT* 9

A. Requiring a New Trial Where The Scientific Evidence Does Not Support a Plaintiff's Case Is Wasteful of the Courts' and the Defendants' Resources 9

B. Requiring Consideration of Evidence That Is Not Relevant and Reliable Undermines *Daubert* 11

CONCLUSION 13

TABLE OF AUTHORITIES

Page(s)

Cases

Aloe Coal Co. v. Clark Equipment Co., 816 F.2d 110 (3rd Cir. 1987), *cert. denied*, 484 U.S. 853 (1987) 6
Anderson v. Liberty Lobby, Inc., 477 U.S. 242 (1986) . . 7
Conde v. Velsicol Chemical Corp., 24 F.3d 809 (6th Cir. 1994) 7
Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995) 8, 10
Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993) . . . . . *passim*
Douglass v. Eaton Corp., 956 F.2d 1339 (6th Cir. 1992) 6
Elbert v. Howmedica, Inc., 143 F.3d 1208 (9th Cir. 1998) 8
General Electric Co. v. Joiner, 118 S.Ct. 512 (1997) 3
Jackson v. Pleasant Grove Health Care Ctr., 980 F.2d 692 (11th Cir. 1993) 6
Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153 (3d Cir. 1993) 4, 6, 10
Midcontinent Broadcasting Co. v. North Cent. Airlines, Inc., 471 F.2d 357 (8th Cir. 1973) 6
Montgomery Ward & Co. v. Duncan, 311 U.S. 243 (1940) 5
Neely v. Eby Construction Co., 386 U.S. 317 (1967) 5

Schudel v. General Electric Co.,
120 F.3d 991 (9th Cir. 1997),
cert. denied, 118 S.Ct. 1560 (1998) 8
Sumitomo Bank v. Product Promotions, Inc.,
717 F.2d 215 (5th Cir. 1983) 6

Rules

Fed. R. Civ. P. 1 5
Fed. R. Civ. P. 50 . . . . . 4, 5, 7
Fed. R. Civ. P. 50(a)(1) 5
Fed. R. Civ. P. 50(b) . . . . . *passim*
Fed. R. Civ. P. 56 7
Fed. R. Evid. 702 . . . . . 3, 5, 6, 8, 11
Sup. Ct. R. 37.6 1

Miscellaneous

American Medical Association, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988) 11
Marcia Angell, *Science on Trial* 204 (1996) 12
G. Michael Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 Creighton L. Rev. 939 (1996) 7
Steven Garber, The Institute for Civil Justice, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 142 (1993) 11

Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395 (Dec. 15, 1989) 11

W. Kip Viscusi, Michael J. Moore, & James Albright, *The Effect of Products Liability Litigation on Innovation: A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418 (1994) 10

9A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2521 (2d ed. 1994) 4 5

In The

Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-245

HOWMEDICA, INC., A DIVISION OF
PFIZER HOSPITAL PRODUCTS GROUP, INC.,

Petitioner,

v.

GEORGE E. ELBERT,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF THE PETITION FOR WRIT OF CERTIORARI

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits this brief *amicus curiae* in support of the petition for a writ of certiorari filed by Howmedica, Inc.[1]

---

[1] Pursuant to Supreme Court Rule 37.6, PhRMA hereby states that no counsel for a party has authored this brief in whole or in part, and that no person or entity other than PhRMA or its members has made a monetary contribution to the preparation or submission of this brief. Petitioner Howmedica, Inc., is a subsidiary of Pfizer Inc., which is a PhRMA member.

INTEREST OF THE *AMICUS CURIAE*

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA's member companies invest nearly $21 billion annually in discovering and developing new medicines. These companies are the source of nearly all new drugs that are discovered and marketed throughout the world.

The pharmaceutical industry is based on science, from the discovery of promising new chemical entities through their testing, development, and distribution. Science also must play a central role in product liability cases alleging injury from these products. Conveying scientific information to a jury under these circumstances necessarily requires expert testimony. Unless unqualified experts and unreliable scientific theories are excluded, juries in these complex cases may award damages that are not founded on reliable scientific information. Similarly, unless cases determined post-trial to lack relevant and reliable evidence to support a plaintiff's position are resolved expeditiously, courts and pharmaceutical companies will be required to expend their limited resources on unnecessary and unwarranted litigation.

The Ninth Circuit's requirements that excluded evidence be considered under Rule 50(b) and that post-trial exclusion of expert testimony be followed by a new trial undermine the trial court's discretion to conclude cases expeditiously when they are not based on *relevant* and *reliable* scientific testimony. Because pharmaceutical litigation invariably requires trial courts to review expert scientific testimony, and because the cost of defending against meritless lawsuits deters innovation and the availability of medications, PhRMA is filing this brief in support of the petition for a writ of certiorari.

INTRODUCTION AND SUMMARY

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), this Court held that Fed. R. Evid. 702 "assign[s] to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." 509 U.S. at 597. *Daubert* directs the trial court to grant summary judgment or judgment as a matter of law if it determines that the evidence is insufficient to support a verdict for the plaintiff. *Id.* at 596. *General Electric Co. v. Joiner*, 118 S.Ct. 512 (1997), which followed *Daubert*, underscores the importance of protecting the trial court's discretion to make determinations concerning the admissibility of scientific testimony. *Daubert* and *Joiner* confirm that the trial court has both the authority and the responsibility to ensure that scientific disputes are resolved based solely on relevant and reliable scientific testimony.

Adherence to the principles recognized in *Daubert* and *Joiner* is equally important at the post-trial stage of litigation. If the trial or appellate court determines that scientific evidence was improperly admitted under Fed. R. Evid. 702, and that a jury's verdict therefore was based on unreliable expert testimony, the error should be corrected fairly and expeditiously. Accordingly, the trial court should not be required to consider unreliable and inadmissible testimony under Fed. R. Civ. P. 50(b). Nor should the trial court be required to conduct a new trial. Instead, the trial court should have the option of entering judgment as a matter of law under Rule 50(b) if it determines, in its proper exercise of discretion, that a plaintiff can produce no competent scientific evidence to support an essential element of the plaintiff's claim.

Protecting the trial court's discretion under *Daubert* is particularly important to the pharmaceutical industry. Pharmaceutical manufacturers face product liability claims that

typically require expert testimony on complex scientific issues. Although it is obviously preferable for the trial court to rule that unreliable evidence is inadmissible prior to trial, in some cases trial courts may reconsider *Daubert* rulings after trial, and in others the trial court's ruling may be reversed on appeal. Requiring a new trial in every instance — even when the admissible scientific evidence cannot support a verdict for the plaintiff — unnecessarily subjects defendants, including pharmaceutical manufacturers, to additional burdensome and costly litigation.

For this reason, PhRMA urges this Court to grant the petition in this case, reverse the Ninth Circuit's decision, and adopt the flexible approach articulated by the Third Circuit in *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993), which accords discretion to the trial court to determine the appropriate course following a post-trial determination that evidence was improperly admitted during trial.

REASONS FOR GRANTING THE PETITION

I. THE NINTH CIRCUIT'S INTERPRETATION OF RULE 50(b) CONFLICTS WITH DECISIONS OF THE THIRD CIRCUIT AND UNDERMINES THIS COURT'S DECISION IN *DAUBERT*.

A. The Ninth Circuit's Decision Misinterprets Rule 50(b) And Conflicts With Decisions of the Third Circuit.

The Ninth Circuit's determination that Fed. R. Civ. P. 50(b) requires consideration of evidence that was improperly admitted during trial rests on a misunderstanding of that rule. Rule 50 is a "judicial control device[]" adopted to permit trial courts to remove from the jury's consideration "cases or issues when the facts are sufficiently clear that the law requires a particular result." 9A Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 2521, at

240 (2d ed. 1994). The purpose of the rule is "to speed litigation and avoid unnecessary retrials." *Neely v. Eby Construction Co.*, 386 U.S. 317, 326 (1967). *See also Montgomery Ward & Co. v. Duncan*, 311 U.S. 243, 250 (1940). In accordance with that purpose, this Court held in *Neely* that an appellate court may direct entry of a judgment when it determines that the evidence was insufficient to support the jury's verdict.

Rule 50 requires entry of judgment as a matter of law if "there is no legally sufficient evidentiary basis for a reasonable jury to find for that party on that issue." Fed. R. Civ. P. 50(a)(1). "The question is not whether there is literally no evidence supporting the party against whom the motion is directed but whether there is evidence upon which the jury *properly* could find a verdict for that party." Wright & Miller § 2524, at 253-254 (emphasis added). The standard is the same whether the Rule 50 motion is made before or after the case is submitted to the jury. *Id.* § 2537, at 347.

Evidence that fails to meet the requirements of Fed. R. Evid. 702 is not admissible. Such evidence is therefore not "legally sufficient" within the meaning of Rule 50, and a jury's verdict in reliance on such evidence is not proper. Requiring courts to consider such evidence under Rule 50(b) does not speed litigation or avoid unnecessary trials, but instead does precisely the opposite, contrary to the purposes of Rule 50. *See also* Fed. R. Civ. P. 1 (Federal Rules of Civil Procedure "shall be construed . . . to secure the just, speedy, and inexpensive determination of every action.").

There is a conflict among the circuits on this important issue. The Third Circuit has held that it is inappropriate to consider excluded testimony under Rule 50(b), and has upheld the trial court's discretion to determine, based on a record containing only admissible evidence, the fair and expeditious remedy for the improper admission of evidence at trial.

Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153; *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110, 115 (3rd Cir. 1987), *cert. denied*, 484 U.S. 853 (1987). The Third Circuit recognized that other courts of appeals have held to the contrary, but correctly noted the absence of any "reasoned elaboration to support [the] thesis that '[i]n ruling on the sufficiency of evidence the trial court must take the record as presented to the jury and cannot enter judgment on a record altered by the elimination of incompetent evidence.'" *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d at 115 (internal citation omitted).[2]

B. The Ninth Circuit's Decision Undermines the Principles of *Daubert*.

The Ninth Circuit's conclusion that Rule 50(b) requires consideration of inadmissible expert testimony is contrary to this Court's decision in *Daubert*. *Daubert* held that Fed. R. Evid. 702 requires trial judges to perform the role of "gatekeeper," screening scientific testimony to ensure that it is relevant and reliable. 509 U.S. 589, 597.[3] This gatekeeping function entails both a determination that a

---

[2] Other courts of appeals have taken the same position as the Ninth Circuit. *See Jackson v. Pleasant Grove Health Care Ctr.*, 980 F.2d 692 (11th Cir. 1993); *Douglass v. Eaton Corp.*, 956 F.2d 1339 (6th Cir. 1992); *Sumitomo Bank v. Product Promotions, Inc.*, 717 F.2d 215 (5th Cir. 1983); *Midcontinent Broadcasting Co. v. North Cent. Airlines, Inc.*, 471 F.2d 357 (8th Cir. 1973).

[3] Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

Fed. R. Evid. 702.

witness has the requisite qualifications to testify to the matters at issue and that the opinion being asserted is scientifically reliable. If either of these components is lacking, the evidence must be excluded.

In *Daubert*, this Court emphasized the duty of the trial court to grant summary judgment or judgment as a matter of law if the evidence presented is too insubstantial to support a verdict in favor of plaintiff. 509 U.S. at 596.

Daubert directs trial courts to exercise their discretion to grant judgment as a matter of law — under either Rule 50 or Rule 56[4] — "in the event the trial court concludes that the scintilla of evidence presented supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true." 509 U.S. at 596. That admonition has been followed by several federal circuit and district courts.[5] Despite *Daubert*, the Ninth Circuit held in

---

[4] Rule 56 directs the trial court to grant summary judgment if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56. The standard for granting summary judgment "mirrors" the standard applied under Rule 50: "[T]he inquiry under each is the same: whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 251-252 (1986).

[5] *See, e.g., Conde v. Velsicol Chemical Corp.*, 24 F.3d 809 (6th Cir. 1994) (holding that, where expert testimony is insufficient to permit a reasonable juror to conclude that the position taken is more likely than not true, a verdict may be directed or summary judgment granted even over expert testimony in evidence); *See also* G. Michael Fenner, *The Daubert Handbook: The Case, Its Essential Dilemma, and Its Progeny*, 29 Creighton L. Rev. 939, 1084-1085 (1996) (listing all cases in which federal courts have granted summary judgment or directed a verdict in accordance with the Supreme Court's holding in *Daubert*).

this case that the magistrate judge "erred in excluding the erroneously admitted evidence when deciding Howmedica's Rule 50(b) motion after remand." *Elbert v. Howmedica, Inc.*, 143 F.3d 1208, 1209 (9th Cir. 1998); Pet. App. 3. The Ninth Circuit's direction to the trial court to consider inadmissible scientific testimony is inconsistent with *Daubert's* mandate to the trial court to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable," 509 U.S. at 589, and to end litigation based on scientifically invalid evidence at its earliest stage.[6]

The Ninth Circuit's decision in this case relies on *Schudel v. General Electric Co.*, 120 F.3d 991 (9th Cir. 1997), *cert. denied*, 118 S.Ct. 1560 (1998), a decision that further illustrates the tension between the Ninth Circuit's position and *Daubert*.[7] In *Schudel*, the trial court improperly permitted the jury to consider an unproven scientific theory. After the jury in *Schudel* returned a verdict in favor of plaintiff, the trial

---

[6] Indeed, the Ninth Circuit itself initially followed this Court's direction when considering the *Daubert* case on remand. Rather than remanding the case to the district court, the Ninth Circuit concluded that "the interests of justice and judicial economy" favored the appellate court's analysis under the new *Daubert* standard of the evidence previously submitted in the trial court. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995), *cert. denied*, 516 U.S. 869 (1995). The Court determined that the evidence could not have satisfied the new standard and would thus have been inadmissible under Fed. R. Evid. 702. *Id.* at 1322. Accordingly, the Ninth Circuit affirmed the district court's prior grant of summary judgment for defendant. *Id.* The Ninth Circuit's decision on remand in *Daubert* was sensible, and it makes even more sense to give the trial court, which observed the first trial and is familiar with the issues and the parties, discretion to decide whether a *Daubert* error warrants a new trial.

[7] The petition for a writ of certiorari in *Schudel* was filed by the plaintiffs, and did not present the question presented by the petition in this case.

court held that the testimony should have been excluded under *Daubert*. The trial court found the remaining evidence insufficient to support the jury verdict and therefore granted judgment for defendant under Rule 50(b). On appeal, the Ninth Circuit agreed that the evidence should have been excluded under *Daubert* but nevertheless held that the trial court had erred in failing to consider that evidence in its Rule 50(b) determination.

II. PHARMACEUTICAL PRODUCT LIABILITY CASES ILLUSTRATE THE IMPORTANCE OF GRANTING COURTS APPROPRIATE POST-TRIAL DISCRETION TO APPLY THE PRINCIPLES OF *DAUBERT*.

Product liability claims brought against pharmaceutical companies typically rely on scientific testimony. The pharmaceutical industry therefore has a substantial interest in ensuring that only relevant and reliable scientific testimony is admitted at trial. If scientific testimony that is not relevant or reliable is incorrectly admitted at trial, it is also important to ensure that the post-trial proceedings permit an efficient and just resolution of the case. The Ninth Circuit's decision in the instant case undermines these interests.

A. Requiring a New Trial Where The Scientific Evidence Does Not Support a Plaintiff's Case Is Wasteful of the Courts' and the Defendants' Resources.

The Ninth Circuit's decision requires trial courts and litigants to engage in an exercise in legal and factual futility. Although there may be situations in which a plaintiff would have been able to substitute a qualified expert to replace the disqualified expert if the trial court's initial evidentiary ruling had been correct, these situations are likely to be few and far between. As the Third Circuit pointed out, there is "no reason to suppose that a litigant would hold back significant

evidence at trial." *Lightning Lube*, 4 F.3d at 1199. The instant case bears this out: on remand, Respondent did not seek to substitute a qualified expert on the issues of negligence and breach of warranty.

The Third Circuit's observation is true of most other pharmaceutical cases as well, which typically turn on an expert's scientific theory of causation. Once a plaintiff's theory has been held to be inadmissible under *Daubert*, it is highly unlikely that plaintiff will be able to offer a new, admissible theory with which to prove causation.[8] Notwithstanding this predictable result, the Ninth Circuit's ruling requires that a second trial take place.[9] Such a futile exercise wastes judicial resources and subjects the pharmaceutical industry — which already faces substantial litigation burdens[10] — to the additional cost and burden of

---

[8] As the Ninth Circuit noted in *Daubert*:

> [T]o augment the substantive testimony as to causation [on remand to the trial court] would require the experts to change their conclusions altogether. Any such tailoring of the experts' conclusions would, at this stage of the proceedings, fatally undermine any attempt to show that these findings were "derived by the scientific method." Plaintiffs' experts must, therefore, stand by the conclusions they originally proffered . . . .

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1322.

[9] Even under the Ninth Circuit's ruling, if it is clear after further development of the facts and witnesses that the plaintiff cannot present scientific evidence that is sufficient to support a favorable verdict under *Daubert*, the trial court should be permitted to enter summary judgment in favor of the defendant.

[10] *See* W. Kip Viscusi, Michael J. Moore, & James Albright, *The Effect of Products Liability Litigation on Innovation: A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most

defending against a claim that the trial court has previously determined to be unsupported by competent scientific evidence. The expenses entailed in defending against meritless claims ultimately deter research and innovation.[11]

B. Requiring Consideration of Evidence That Is Not Relevant and Reliable Undermines *Daubert*.

The Ninth Circuit's interpretation of Rule 50(b) requires judicial consideration of evidence that has been held to be inadmissible under Rule 702 and *Daubert*. Because of the significance of the *Daubert* decision in the context of pharmaceutical litigation, the Ninth Circuit's ruling is of particular concern to the industry.

Pharmaceutical litigation often involves consideration of complex scientific testimony. As Marcia Angell, M.D., the

---

innovative industries in the economy, has been particularly hard hit by the surge in liability costs.").

[11] *See* Steven Garber, The Institute for Civil Justice, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 142 (1993) ("Effects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries."); Richard J. Mahoney & Stephen E. Littlejohn, *Innovation on Trial: Punitive Damages Versus New Products*, 246 Science 1395, 1397 (Dec. 15, 1989) ("The result of this liability expansion has been a slowing of innovation in entire fields of inquiry, especially in those having to do with health care."). *See also* American Medical Association, *Report of the Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988), finding that:

> Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks.

Executive Editor of the New England Journal of Medicine, has noted, such testimony is particularly difficult for juries to evaluate, since they usually have no special expertise in the area.[12] Compounding this inherent difficulty, the tort system encourages lawyers under contingency fee arrangements to bring meritless suits, impose burdensome defense costs on defendants, and seek to collect quick settlements.[13] As a result "scientific testimony in the courtroom is often at most only marginally related to scientific evidence. . . . [causing] a growing gap between scientific reality and what passes for it in the courtroom."[14]

As Dr. Angell noted, "[t]he *Daubert* decision was a brave step toward remedying the situation,"[15] because it grants the trial court the authority to exclude from the jury's consideration scientific testimony that is not relevant and reliable, thereby preventing the jury from being swayed by emotional appeals premised on "junk science."

Where the trial court errs and admits testimony that should have been excluded under *Daubert*, this evidence should not be given weight in the context of a Rule 50(b) motion. Instead, once a determination has been made that the evidence was admitted in error, the trial court should be able to exclude the evidence from further consideration. If the excluded evidence was the only evidence relied on by the plaintiff regarding an essential element of its claim, and certainly if the plaintiff cannot show that it was harmed by the district court's erroneous ruling, the trial court should be able

---

[12] Marcia Angell, *Science on Trial* 204 (1996).

[13] *Id.* at 203.

[14] *Id.* at 132.

[15] *Id.*

to end the case by granting judgment as a matter of law in favor of the defendant.

The trial court's ability to exclude evidence that does not meet *Daubert* standards from consideration under Rule 50(b) safeguards this Court's holding in *Daubert* and minimizes the costs of baseless litigation by permitting courts to grant judgment as a matter of law and conclude litigation where insufficient scientific evidence exists to warrant a second trial.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Of Counsel:

Russel A. Bantham
Marjorie E. Powell
PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA
1100 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 835-3400

Bruce N. Kuhlik
Counsel of Record
Theodore Voorhees, Jr.
Robert A. Long, Jr.
Gail H. Javitt
COVINGTON & BURLING
1201 Pennsylvania Ave., N.W.
P.O. Box 7566
Washington, D.C. 20044
(202) 662-6000

Counsel for Amicus Curiae

September 8, 1998

(4)

FILED
SEP 18 1998
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 98-245

In The

Supreme Court of the United States

October Term, 1997

HOWMEDICA, INC., a Division of
Pfizer Hospital Products Group, Inc.,

Petitioner,

vs.

GEORGE E. ELBERT,

Respondent.

**On Petition For Writ Of Certiorari
To The United States Court Of Appeals
For The Ninth Circuit**

PETITIONER HOWMEDICA, INC.'S REPLY TO RESPONDENT GEORGE E. ELBERT'S OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

GOODSILL ANDERSON QUINN & STIFEL
JACQUELINE EARLE*
MARGARET JENKINS LEONG
1099 Alakea Street, Suite 1800
Honolulu, Hawaii 96813
Ph: (808) 547-5600

Counsel for Petitioner

**Counsel of Record*

COCKLE LAW BRIEF PRINTING CO., (800) 225-6964
OR CALL COLLECT (402) 342-2831

4pp

I. THE SPLIT CANNOT BE RECONCILED.

The Third Circuit Court of Appeals has expressly and emphatically rejected the reasoning set forth in the decision below. *Aloe Coal Co. v. Clark Equipment Co.*, 816 F.2d 110 (3d Cir.), *cert. denied*, 484 U.S. 853, 108 S. Ct. 156, 98 L.Ed.2d 111 (1987); *Lightening Lube, Inc. v. Witco Corp.*, 4 F.3d 1153 (3d Cir. 1993). The circuit courts are in conflict, since the Ninth Circuit and others have adopted a *per se* rule that inadmissible evidence must be considered on a motion for judgment, while the Third Circuit has recognized that in most cases improper evidence should be disregarded.

Respondent cites to *dicta* in *Lightening Lube* in an effort to minimize the circuit conflict, but the quoted passage shows only that the Third Circuit would not demand entry of judgment in *all* cases where improper evidence has been admitted. The Third Circuit did not demand that judgment be entered where the record considered without the improper evidence is still sufficient to support the verdict. 4 F.3d at 1199 Fn. 26. The court also reasoned that judgment should not be entered in a case where the evidence presented at trial was shaped or limited by the trial court's initial finding of admissibility. 4 F.3d at 1200. The Third Circuit quite reasonably did not establish a *per se* rule demanding entry of judgment, but it clearly stands in opposition to the Ninth and other circuits by holding that, absent exceptional circumstances, when a motion for judgment is made following trial, improper evidence should be disregarded.

II. THE SPLIT IS AT ISSUE.

Elbert tries to distance his case from the circuit court conflict, but he does not show any reasoned basis for treating it differently simply because the motion for judgment was made following remand. The question presented is the same: must evidence that was erroneously admitted at trial be weighed in determining whether plaintiff has met his burden of production. The Ninth Circuit gave the same answer to the question in the post-trial and post-remand contexts, for precisely the same reason: that a plaintiff may rely on the trial court's initial ruling of admissibility in determining how to present its case to the jury. The split has arisen because the Third Circuit disputes the premise of reliance, and its reasoning applies with equal force following remand.

III. THE SPLIT IS OUTCOME DETERMINATIVE.

Under the Third Circuit's approach, a court considering a motion for judgment should disregard improper evidence except where plaintiff limited its presentation of evidence at trial in reliance on the prior ruling. Since the Ninth Circuit applied its *per se* rule, it did not even inquire into whether Elbert limited his presentation based on the admission of Kayser's testimony. In fact, Elbert's presentation of witnesses was limited by pretrial rulings, and there were no available witnesses he could have called to fill the void if the objection to Kayser's testimony had been sustained during trial. Following remand in this case, the trial court considered the evidence submitted by Elbert and found the record was not sufficient to support a verdict in his favor when the improper

evidence was excised. The only reason this case survived is because of the Ninth Circuit's adherence to the *per se* rule. Petitioner respectfully requests that this Court grant certiorari to reject the *per se* rule, and bring this case to a close.

DATED: Honolulu, Hawaii, September 17, 1998.

Respectfully submitted,

JACQUELINE EARLE
MARGARET JENKINS LEONG
Attorneys for Petitioner
Howmedica, Inc.